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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,397	12/20/2001	George L. Murphy	AMBI:076US	2120

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EXAMINER

SISSON, BRADLEY L

ART UNIT PAPER NUMBER

1634

DATE MAILED: 09/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/029,397	Applicant(s) MURPHY ET AL.	
	Examiner Bradley L. Sisson	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-46 and 48-90 is/are pending in the application.  
     4a) Of the above claim(s) 55-82 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 54 and 83-85 is/are allowed.
- 6) ☒ Claim(s) 1-46, 48-53 and 86-90 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Location of Application*

1. The location of the subject application has changed. The subject application is now located in Workgroup 1630, Art Unit 1634, and has been docketed to Primary Examiner Bradley L. Sisson.

### *Specification*

2. The specification is objected to as documents have been improperly incorporated by reference. In particular, the specification states at page 80 that the documents identified in the following six pages of bibliographic citations “provide exemplary procedural or other details supplementary to those set forth herein, are specifically incorporated herein by reference.” Similar language is found throughout the specification; see, e.g., pages 23, 42, 43, 48, 49, and 51. Such omnibus language fails to specify what specific information applicant seeks to incorporate by reference and similarly fails to teach with detailed particularity just where that specific information is to be found in each of the cited documents. As set forth in *Advanced Display Systems Inc. v. Kent State University* (Fed. Cir. 2000) 54 USPQ2d at 1679:

Incorporation by reference provides a method for integrating material from various documents into a host document--a patent or printed publication in an anticipation determination--by citing such material in a manner that makes it clear that the material is effectively part of the host document as if it were explicitly contained therein. *See General Elec. Co. v. Brenner*, 407 F.2d 1258, 1261-62, 159 USPQ 335, 337 (D.C. Cir. 1968); *In re Lund*, 376 F.2d 982, 989, 153 USPQ 625, 631 (CCPA 1967). **To incorporate material by reference, the host document must identify with detailed particularity what specific material it**

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**incorporates and clearly indicate where that material is found in the various documents.** See *In re Seversky*, 474 F.2d 671, 674, 177 USPQ 144, 146 (CCPA 1973) (providing that incorporation by reference requires a statement “clearly identifying the subject matter which is incorporated and where it is to be found”); *In re Saunders*, 444 F.2d 599, 602-02, 170 USPQ 213, 216-17 (CPA 1971) (reasoning that a rejection or anticipation is appropriate only if one reference “expressly incorporates a particular part” of another reference); *National Latex Prods. Co. v. Sun Rubber Co.*, 274 F.2d 224, 230, 123 USPQ 279, 283 (6<sup>th</sup> Cir. 1959) (requiring a specific reference to material in an earlier application in order to have that material considered a part of a later application); cf. *Lund*, 376 F.2d at 989, 13 USPQ at 631 (holding that **a one sentence reference to an abandoned application is not sufficient to incorporate from the abandoned application into a new application**). (Emphasis added.)

Attention is also directed to MPEP 608.01(p)I, which, in pertinent part, is reproduced

below:

Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. In *re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). In addition to other requirements for an application, the referencing application should include an identification of the referenced patent, application, or publication. Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found. (Emphasis added)

Accordingly, the cited documents are not considered to have been properly incorporated by reference and as such, have not been considered with any effect towards their fulfilling, either in part or in whole, the enablement, written description, or best mode requirements of 35 USC 112, first paragraph.

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-46, 48-53, and 86-90 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 1 provides for the use of nontargeted nucleic acids in the depleted sample, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Claims 2-46, 48-53, and 86-90, which depend from claim 1, fail to overcome this issue and are similarly rejected.

7. Claims 1-46, 48-53, and 86-90 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1, 9-11, 14-16, 19-31, 33, and 35-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,635,352 (Urdea et al.) in view of US Patent 5,639,428 (Cottingham) and US Patent 5,256,536 (Miyada et al.).

12. Urdea et al. teach all of the limitations of the method for isolating a targeted nucleic acid from a sample recited in Claim 1 except these authors do not explicitly teach discarding the targeted nucleic acid. See the figures of Urdea et al. and note Column 27 wherein these authors teach repeatedly washing the wells of their plates to remove

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unhybridized nucleic acids (i.e. isolating the targeted nucleic acid). As regards the limitation not taught by Urdea et al. (i.e. these authors do not teach discarding the targeted nucleic acid), note that, as evidenced by Cottingham, it was well known in the art at the time of the invention to discard the a tube/composition comprising a molecular biological assay once the assay is completed. See, for example, the abstract. As regards the limitations set forth in Claims 9-11, see at least for example the tables in Columns 17-20 of Urdea et al. As regards Claims 14-16, see at least for example Figure 8 of Urdea et al.

13. Miyada et al., column 7, disclose performing an assay whereby a sample is depleted of a target nucleic acid via sandwich hybridization. The target-depleted sample is then used in subsequent assays.

14. In view of these findings and absent an unexpected result, it would have been prima facie obvious to the ordinary artisan at the time of the invention to modify Urdea et al. wherein after the assay is completed the assay composition comprising the targeted nucleic acid is discarded (i.e. the targeted nucleic acid is discarded; Miyada et al.). The ordinary artisan would have been motivated to make this modification because by performing subtractive hybridization one is able to eliminate similar/competing nucleic acids from the sample, and in turn, be able to detect other nucleic acids with a high degree of confidence. Furthermore, once the assay reasonably suggested by Urdea et al. in view of Cottingham is finished there is no need to retain the isolated nucleic acid.

15. As regards Claims 19-31, it is noted that neither Urdea et al. nor Cottingham teach the exact location on the target nucleic acid wherein the bridging oligos hybridize. However, absent an unexpected result, with the positions/sequences recited, it would

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have been prima facie obvious to the ordinary artisan at the time of the invention that the bridging oligos could be designed, with a reasonable expectation of success, to hybridize anywhere on the targeted nucleic acid.

The aspect of using sequences of specific lengths, and/or percent identity, or in certain binding relationships is a matter of routine optimization when, as shown above, all of the elements of the claimed method were known in the art at the time of filing. In support of this position, attention is directed to the decision in *In re Aller, Lacey, and Hall*, 105

USPQ 233 (CCPA 1955):

Normally, it is to be expected that a change in temperature, or in concentration, or in both, would be an unpatentable modification. Under some circumstances, however, changes such as these may impart patentability to a process if the particular ranges claimed produce a new and unexpected result, which is different in kind, and not merely in degree from the results of the prior art. *In re Dreyfus*, 22 C.C.P.A. (Patents) 830, 73 F.2d 931, 24 USPQ 52; *In re Waite et al.*, 35 C.C.P.A. (Patents) 1117, 168 F.2d 104, 77 USPQ 586. Such ranges are termed "critical" ranges, and the applicant has the burden of proving such criticality. *In re Swenson et al.*, 30 C.C.P.A. (Patents) 809, 132 F.2d 1020, 56 USPQ 372; *In re Scherl*, 33 C.C.P.A. (Patents) 1193, 156 F.2d 72, 70 USPQ 204. However, even though applicant's modification results in great improvement and utility over the prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art. *In re Sola*, 22 C.C.P.A. (Patents) 1313, 77 F.2d 627, 25 USPQ 433; *In re Normann et al.*, 32 C.C.P.A. (Patents) 1248, 150 F.2d 708, 66 USPQ 308; *In re Irmscher*, 32 C.C.P.A. (Patents) 1259, 150 F.2d 705, 66 USPQ 314. More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Swain et al.*, 33 C.C.P.A. (Patents) 1250, 156 F.2d 239, 70 USPQ 412; *Minnesota Mining and Mfg. Co. v. Coe*, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; *Allen et al. v. Coe*, 77 App. D. C. 324, 135 F.2d 11, 57 USPQ 136. (Emphasis added)

16. Please note MPEP 2111.03 as regards the meaning of the transitional phrase "comprising" used in Claim 1. The transitional phrases "comprising", "consisting essentially of" and "consisting of" define the scope of a claim with respect to what



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unrecited additional components or steps, if any, are excluded from the scope of the claim. The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by" is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986)., *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981)\*, *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts").

17. Claims 2-8 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,635,352 (Urdea et al.), US Patent 5,639,428 (Cottingham) and US Patent 5,256,536 (Miyada et al.) as applied to claims 1, 9-11, 14-16, 19-31, 33, and 35-40 above, and further in view of US Patent 5,541,308 (Hogan et al.).

18. Urdea et al. in view of Cottingham and Miyada et al., teach all of the limitations of Claims 2-8 and 32 except these authors do not explicitly teach isolating rRNA.

However, as evidenced by Hogan et al. it was well known in the art at the time of the invention to detect rRNA as a means to detect and/or quantify non-viral organisms.

Please note that Hogan et al. explicitly teach detecting rRNA sequences from both eukaryotic and prokaryotic organisms reciting each of the rRNA types listed in Claim 3.

See, at least for example, Column 2, beginning at about line 34. Also as regards the limitations of Claim 5, note that Hogan et al. teach detecting fungal (eukaryotic) rRNA

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sequences (18S and 28S). As regards 7-8 please note that Hogan et al. list *Enterococci* (gram positive bacteria) and both *E. coli* and *Neisseria gonorrhoeae* (gram negative bacteria).

19. In view of these findings and absent an unexpected result, it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to modify the assay reasonably suggested by Urdea et al., Cottingham and Miyada et al., wherein the assay is used to deplete a sample of a target nucleic acid wherein said target nucleic acid is a rRNA sequences from both eukaryotic and prokaryotic organisms recited by Hogan et al. Please note that substitution of one well known method/reagent with known properties for a second well known method/reagent with well known properties would have been prima facie obvious to the ordinary artisan at the time of the invention in the absence of an unexpected result. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior ad elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

20. As regards Claims 4 and 32, it is believed by the examiner that after reviewing the specification and a limited sequence search, that all of the rRNA sequences recited were known and are presumed to be present in the prior art. In view of this finding and absent an unexpected result, it would have been prima facie obvious to the ordinary artisan at the time of the invention to modify the assay reasonably suggested by Urdea et al. in view of Cottingham and Hogan et al. wherein the assay is used to isolate and detect the known rRNA sequences recited in Claim 4. Again, please note that substitution of one well

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known method/reagent with known properties for a second well known method/reagent with well known properties would have been prima facie obvious to the ordinary artisan at the time of the invention in the absence of an unexpected result. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

21. Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,635,352 (Urdea et al.), US Patent 5,639,428 (Cottingham) and US Patent 5,256,536 (Miyada et al.) as applied to claims 1, 9-11, 14-16, 19-31, 33, and 35-40 above, and further in view of US Patent 5,324,632 (Weisburg et al.).

22. Urdea et al. in view of Cottingham and Miyada et al., teach all of the limitations of Claims 12-13 except these authors do not explicitly teach isolating the target sequence through use of a polypurine or polypyrimidine. However, as evidenced by Weisburg et al., it was well known in the art at the time of the invention, to hybridize two sequences via long stretches of polypurines or polypyrimidines. Absent an unexpected result, it would have been prima facie obvious to the ordinary artisan at the time of the invention to modify the assay reasonably suggested by Urdea et al. in view of Cottingham wherein the assay comprises a bridging region or a capture region that is composed of only purines or only pyrimidines.

23. Please note that substitution of one well known method/reagent with known properties for a second well known method/reagent with well known properties would

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have been prima facie obvious to the ordinary artisan at the time of the invention in the absence of an unexpected result. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

24. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,635,352 (Urdea et al.), US Patent 5,639,428 (Cottingham) and US Patent 5,256,536 (Miyada et al.) as applied to claims 1, 9-11, 14-16, 19-31, 33, and 35-40 above, and further in view of US Patent 6,270,973 (Lewis et al.).

25. Urdea et al. in view of Cottingham and Miyada teach all of the limitations of Claims 17 except these authors: Do not teach multiplexing (i.e. isolating two or more target nucleic acids). However, as evidenced by Lewis et al. it was well known in the art at the time of the invention to multiplex hybridization type assays in order to simultaneously detect two or more target nucleic acids thereby increasing productivity. In view of these findings and absent an unexpected result, it would have been prima facie obvious to the ordinary artisan at the time of the invention to modify the assay reasonably suggested by Urdea et al. in view of Cottingham wherein the assay is multiplexed. See, at least for example, Column 26, beginning at about line 60 wherein Lewis et al., define multiplexing.

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26. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,635,352 (Urdea et al.), US Patent 5,639,428 (Cottingham), US Patent 5,256,536 (Miyada et al.), and US Patent 6,270,973 (Lewis et al.) as applied to claims 1, 9-11, 14-17, 19-31, 33, and 35-40 above, and further in view of US Patent 5,541,308 (Hogan et al.).

27. Urdea et al. in view of Cottingham, Miyada et al., and Lewis et al. teach all of the limitations of Claim 18 except these authors do not teach, as regards Claim 18, an embodiment wherein one of the targeted nucleic acids is the largest rRNA in the sample while the second targeted nucleic acids is the second largest rRNA in the sample. However, Hogan et al. do teach detecting either the 18S or the 28S rRNA of fungi or the 16S and 23S of bacteria. In view of these findings and absent an unexpected result, it would have ' been prima facie obvious to the ordinary artisan at the time of the invention to modify the assay reasonably suggested by Urdea et al. in view of Cottingham and Lewis et al. wherein both the fungal 28S rRNA and bacterial 23S rRNA are simultaneously isolated and detected in order to quickly and efficiently determine the cause of a particular illness in a patient. See at least for example, Column 2, beginning at about line 34 of Hogan et al.

28. Claims 41-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,635,352 (Urdea et al.), US Patent 5,639,428 (Cottingham), and US Patent 5,256,536 (Miyada et al.) as applied to claim 1, 9-11, 14-16, 19-31, 33, and 35-40 above, and further in view of US Patent 5,512,439 (Hornes et al.).

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Urdea et al. in view of Cottingham and Miyada et al., teach all of the limitations of Claim 41-45 except these authors do not teach an embodiment wherein the non reacting structure comprises a bead comprising a material selected from a defined group which includes cellulose. However, as the use of cellulose covered magnetic beads was well known at the time of the invention as evidenced by Hornes et al., it would have been, absent an unexpected result, *prima facie* obvious to the ordinary artisan at the time of the invention to modify the assay reasonably suggested by Urdea et al. in view of Cottingham and Miyada wherein cellulose covered magnetic beads are utilized. Please note that substitution of one well known method/reagent with known properties (i.e. the magnetic beads of Hornes et al.) for a second well known method/reagent with well known properties (i.e. microtiter plates) would have been *prima facie* obvious to the ordinary artisan at the time of the invention in the absence of an unexpected result. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09. As regards Claim 44, wherein the nonreacting structure is biotin, please note that the beads of Hornes et al. may comprise biotin.

29. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,635,352 (Urdea et al.), US Patent 5,639,428 (Cottingham), US Patent 5,256,536 (Miyada et al.), and US Patent 5,512,439 (Hornes et al.) as applied to claim 1, 9-11, 14-16, 19-31, 33, and 35-45 above, and further in view of US Patent 5,633,134 (Shuber).

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Urdea et al. in view of Cottingham Miyada et al., and Hornes et al. teach all of the limitations of Claim 46 except these authors do not teach using a hybridization buffer comprising TMAC or TEAC. However, as the use of hybridization buffers comprising TMAC was well known at the time of the invention, as evidenced by Shuber et al., it would have been, absent an unexpected result, prima facie obvious to the ordinary artisan at the time of the invention to modify the assay reasonably suggested by Urdea et al. in view of Cottingham and Hornes et al. wherein the hybridization buffer for the assay comprised TMAC. Please note that substitution of one well known method/reagent with known properties for a second well known method/reagent with well known properties would have been prima facie obvious to the ordinary artisan at the time of the invention in the absence of an unexpected result. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

*Allowable Subject Matter*

30. Claims 54 and 83-85 are allowed.

*Conclusion*

31. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

32. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

33. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

34. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

35. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you



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have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "B. L. Sisson". The signature is fluid and cursive, with the first name "B." and last name "Sisson" clearly distinguishable.

Bradley L. Sisson  
Primary Examiner  
Art Unit 1634

BLS  
30 August 2004